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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,499	02/13/2002	Evangelyn C. Alocilja	MSU 4.1-587	4246

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/074,499	ALOCILJA ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-10,14-16,18,19,21,22,24 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-10,14-16,18,19,21,22,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 1, 7, 8, 14, 22, 24 and 26 are acknowledged.

Currently, claims 1 – 3, 7 – 10, 14 – 16, 18, 19, 21, 22, 24, and 26 are pending and under examination.

Withdrawn Rejections

All previous rejections of the claims under 35 U.S.C. 103(a) are withdrawn in view of Applicant's amendments filed February 26, 2007.

Response to Arguments

Applicant's arguments filed February 26, 2007 with respect to the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over the prior art references of Kim et al. in view of Sigal et al. have been considered. In particular, Applicant argues (see p13-17) that the Kim et al. reference, as well as the combination of the Kim et al. reference in view of Sigal et al., fails to teach the "direct" labeling of the antibody, i.e. the second capture reagent, with the conductive polymer, wherein the teachings of both Kim et al. and Sigal et al. result in the conductive polymer being bound to the colloidal gold particle or the semiconductive particle and not directly bound to the antibody. However, Kim et al. do discuss the "direct labeling" of the antibody with the conductive polymer, wherein Kim et al. consider this "direct labeling" to be the non-preferred labeling of the antibody (see "Conclusions" section on page 914, the first 9 lines). This

teaching by Kim et al. of the "direct labeling" of the antibody, even though it is the non-preferred method, reads on Applicant's amended claim 1, and renders Applicant's amended claim 1 obvious over the Kim et al. reference.

Therefore, Applicant's arguments are considered moot in view of the new ground(s) of rejection.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 7-9, 14-16, 18-19, and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al.(Biosensor & Bioelectronics (2000), vol. 14, pp. 907-915).

In the instant claims, Kim et al. teach a conductimetric immunosensor (biosensor device) comprising:

a strip of a membrane (substrate) having at least two sections (zones) wherein a

(1) middle section (first of the zones) contains an antibody (first capture reagent) immobilized (bound) to the membrane (substrate) in a defined area between screen-printed thick film electrodes in an interdigitated structure, wherein the antibodies are immobilized on the interdigitated area comprising silver electrodes, wherein an anode and cathode are separated and the binding complex on the interdigitated structure is formed in between the electrodes (i.e. between electrodes on different sides of the defined area) (see page 911, right column, 1st full paragraph, lines 1-5; and Figure 3, and caption); and

(2) a lower section (second of the zones) containing a glass fiber membrane (fluid transfer medium) for sample application to the middle section (supplying a fluid to the first zone), wherein the lower section comprises a second defined area containing a second antibody (second capture reagent) that is directly bound to an electrically conductive polymer, i.e. polyaniline, or indirectly bound to the electrically conductive polymer through a colloidal gold particle, wherein the electrically conductive polymer, in the form of polyaniline, is created by a standard procedure of oxidative polymerization of aniline monomer in the presence of APS (i.e. polymer formed by oxidative polymerization of monomers) and the electrically conductive polymer has been mixed with the second antibody to form a conjugate, either with or without the colloidal gold particles (electrically conductive particles), wherein when a fluid sample containing an analyte is bound by the second antibody (capture reagent) to form a complex, the complex migrates to the middle section (first zone) of the

membrane (medium) and the analyte is bound by the first antibody (capture reagent) thereby altering a conductivity of the defined area in the middle section as measured between the electrodes to detect the analyte (see pages 909-911; "Conclusions" on page 914; Figures 1 and 3-4, and captions).

Although Kim et al. teach that the preferred embodiment for the second antibody conjugate, which represents a labeling agent, comprises a colloidal gold-antibody conjugate that further includes the electrically conductive polymer on the surface thereof, Kim et al. do teach the "direct labeling" of the antibody with the electrically conductive polymer (see "Conclusions" section on page 914, the first 9 lines). Specifically, Kim et al. state, "This strategy for conductimetric detection could be a better approach than the **direct labeling of the antibody with the polymer**...". This would indicate that such a direct labeling between the antibody and the conductive polymer was well known in the art at the time the invention was made. Therefore, it would have been obvious to utilize the "direct labeling" of the antibody with the electrically conductive polymer as disclosed by Kim et al. to achieve the predictable result of altering a conductivity of the measurement area between electrodes. Further, it would have reasonably been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Additionally, all disclosures of non-preferred embodiments must be considered. *In re Nehrenberg* 126 USPQ 383, *In re Boe* 148 USPQ 507, *In re Lamberti et al.* 192 USPQ 278 (CCPA 1976).

With regards to claims 2, 9, and 15, Kim et al teach a cellulose membrane that is an absorption pad as an upper section of the immunosensor strip (i.e. third zone adjacent to the first zone). See Figures 1 and 3, and captions.

With regards to claims 16, 18-19, and 21, Kim et al teach microwells with sample medium into which the immunostrips were placed (i.e. third zone or pad is applied), as stated above. See page 909, 2nd full paragraph, lines 8-18; and Figure 1 and caption. Since the term "pad" has not been defined in the specification, the instant term is considered to be any substrate capable of containing a liquid sample medium.

With regards to claims 7 and 14, Kim et al also teach that voltage was applied across the electrodes (i.e. electrical means) and that conductimetric detection was performed by a conductivity meter, wherein the measurements can determine a transient response after complex formation between antigen and antibody (i.e. measuring means for determining a change in the conductivity of the first area between and after application of the sample). See page 910, left column, 1st paragraph, lines 5-8; and page 912, right column, 2nd full paragraph, lines 1-4.

Claims 3, 10, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biosensor & Bioelectronics (2000), vol. 14, pp. 907-915), as applied to claims 1, 8, and 14 above, and further in view of Roberts et al (US 5,958,791).

The Kim et al. reference, which was discussed in the 103(a) rejection above, fails to teach a multiple array of first zones each having a first capture reagent with a

different specificity to immobilize one of multiple analytes (claims 22, 24, and 26), and also fail to teach that the first defined area has a dimension between the electrodes of 1.0 mm (claims 3 and 10).

Roberts et al. teach a test device that includes multiple sets of interdigitated electrode arrays with an area of 6mm x 1mm, in order to perform simultaneous multiple analyte detection and assay a test sample for a plurality of analytes (see column 18, lines 53-55; column 24, lines 1-6; and column 25, lines 16-20). In addition, Roberts et al. teach that the test device is a test strip with capillary flow through an absorbent material with a capture region, wherein the capture region contains binding material that can be an antibody (see column 5, lines 29-42 and 55-56; column 11, lines 29-40; and Figure 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kim et al. to include multiple sets of interdigitated electrode arrays with an area of 6mm x 1mm, as taught by Roberts et al., in order to perform simultaneous multiple analyte detection and assay a test sample for a plurality of analytes. The electrode arrays of Roberts et al. have the advantage of allowing multiple tests to be performed at once, thereby cutting down on experimentation time, and providing motivation for combining the electrode arrays with the device of Kim et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including multiple sets of interdigitated electrode arrays with an area of 6mm x 1mm, as taught by Roberts et al., in the device of Kim et al., since Kim et al. teach a test strip with an antibody-layered capture region

on an interdigitated electrode wherein sample can flow up the strip, and the interdigitated electrode arrays of Roberts et al. also include a capture region with immobilized antibody, and are on a test strip that can accommodate capillary flow.

In regards to claim 26, since Kim et al. and Roberts et al. in combination teach a device comprising an array of interdigitated electrodes, the intended use limitation "multiple analytes can be detected simultaneously from the sample by providing a constant current and measuring generated voltages across the area of each of the first zones" is fully capable of being performed by the device.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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